

## PATIENT INFORMATION LEAFLET

### ZIAXE 250 mcg/5 ml solution for i.v. injection

#### For intravenous administration.

Sterile

- **Active ingredient:** Palonosetron (as hydrochloride).

Each 5 ml vial contains 280 micrograms of palonosetron hydrochloride equivalent to 250 micrograms of palonosetron. (Each ml of solution contains 56 micrograms of palonosetron hydrochloride equivalent to 50 micrograms of palonosetron)

- **Excipients:** Mannitol, disodium edetate, trisodium citrate dihydrate, citric acid monohydrate, water for injection, sodium hydroxide solution, and hydrochloric acid solution.

**Read all of this LEAFLET carefully before you start using this medicine because it contains important information for you.**

- *Keep this leaflet. You may need to read it again.*
- *If you have any further questions, ask your doctor or pharmacist.*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *Tell your doctor that you are using this medicine if you attend a doctor or hospital visit during the use of this medicine.*
- *Strictly follow the instructions in this leaflet. Do not take doses **higher** or **lower** than recommended to you.*

#### **In this leaflet:**

- 1. What is ZIAXE and what it is used for***
- 2. What you need to know before you use ZIAXE***
- 3. How to use ZIAXE***
- 4. Possible side effects***
- 5. How to store ZIAXE***

**headlines are included.**

#### **1. What is ZIAXE and what it is used for**

- ZIAXE is a colorless solution for intravenous administration.
- ZIAXE is packed into a glass vial that contains 5 ml of solution. Each vial contains one dose.
- ZIAXE belongs to a group of medicines known as serotonin (5HT<sub>3</sub>) antagonists.
- These have the ability to block the action of the chemical, serotonin, which can cause nausea and vomiting.

- ZIAXE is used for the prevention of nausea and vomiting associated with drug treatment of cancer (chemotherapy) in adults and children older than 1 month of age.

## **2. What you need to know before you use ZIAXE**

### **Do NOT use ZIAXE**

If you are allergic to Palonosetron or any of the other ingredients contained in ZIAXE (refer to the list of excipients).

### **Take SPECIAL CARE with ZIAXE:**

If:

- you have acute bowel obstruction or a history of repeated constipation.
- you are using palonosetron in addition to other medicines that may induce an abnormal heart rhythm such as amiodarone, nifedipine, quinidine, moxifloxacin, erythromycin, haloperidol, chlorpromazine, quetiapine, thioridazine, domperidone.
- you have a personal or family history of alterations in heart rhythm (QT prolongation).
- you have other heart problems.
- you have an imbalance of certain minerals in your blood such as potassium and magnesium which has not been treated.

It is not recommended to take ZIAXE in the days following chemotherapy unless you are receiving another chemotherapy cycle.

Tell your doctor even if these warnings have applied to you at any time in the past.

### **Taking ZIAXE with food and drinks**

Due to the method of administration, ZIAXE does not interact with food and drinks.

### **Pregnancy**

*Ask your doctor or pharmacist before taking this medicine.*

If you are pregnant or think you might be, your doctor will not administer ZIAXE to you unless it is clearly necessary.

It is not known whether ZIAXE will cause any harmful effects when used during pregnancy.

*Tell your doctor or pharmacist right away if you notice that you are pregnant during your treatment.*

### **Breastfeeding**

*Ask your doctor or pharmacist before taking this medicine.*

It is not known whether ZIAXE is found in human milk.

Ask your doctor or pharmacist for advice before using ZIAXE if you are breast-feeding.

### **Driving and using machines**

ZIAXE may cause dizziness, sleepiness or tiredness. If affected, do not drive or use any tools or machines.

### **Important information on some of the ingredients contained in ZIAXE**

No adverse reaction associated with these ingredients is expected unless you are hypersensitive to the excipients contained in ZIAXE.

This medicine contains <1 mmol sodium (23 mg) per vial, i.e., essentially “sodium-free.”

ZIAXE contains 207.5 mg mannitol; however, this quantity does not require any warning.

### **Other medicines and ZIAXE**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- SSRIs (selective serotonin reuptake inhibitors) used to treat depression and/or anxiety including fluoxetine, paroxetine, sertraline, fluvoxamine, citalopram, escitalopram.
- SNRIs (selective noradrenaline reuptake inhibitors) used to treat depression and/or anxiety including venlafaxine and duloxetine.

*Tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.*

## **3. How to use ZIAXE**

### **Instructions for proper use and frequency of dose/administration:**

Your doctor or nurse will normally administer ZIAXE by intravenous injection at a single dose about 30 minutes before the start of chemotherapy.

### **In adults:**

#### **Route and method of administration:**

- ZIAXE is injected via the intravenous route.
- A doctor or nurse will normally inject ZIAXE about 30 minutes before the start of chemotherapy.
- 250 micrograms of ZIAXE is administered intravenously by rapid injection. Discard unused ZIAXE after opening the vial.

### **Different age groups:**

#### **Use in children and adolescents (from 1 month to 17 years of age):**

- The doctor will decide the dose of the drug based on body weight, but the maximum dose is 1500 micrograms.
- ZIAXE will be given intravenously with slow infusion.

**Use in the elderly:**

No dosage adjustment is necessary in elderly patients. Dose is administered upon the doctor's recommendation.

**Special conditions of use****Renal/Hepatic Insufficiency:**

No dosage adjustment other than the dose recommended by a doctor is necessary in patients with kidney insufficiency. Ask your doctor since no data are available for patients with advanced stage renal disease undergoing hemodialysis.

No dosage adjustment other than the dose recommended by a doctor is necessary in patients with impaired liver function.

Unless recommended otherwise by your doctor, follow the instructions listed in this leaflet.

Do not forget to take your medicine on time.

Your doctor will inform you how long your treatment with ZIAXE will last. Do not stop your treatment early, as you will not obtain the desired results.

*If you feel that the effect of ZIAXE is too strong or too weak, consult your doctor or pharmacist.*

**If you take more ZIAXE than you should:**

*If you took more ZIAXE than you should, tell your doctor or pharmacist.*

**If you forget to take ZIAXE:**

Your doctor will decide when the skipped dose will be administered.

It is important to follow the instructions given by your doctor for proper timing of administration of the subsequent dose.

*Do not take a double dose to make up for a forgotten dose.*

**Possible reactions that may occur when treatment with ZIAXE is discontinued:**

Not applicable.

**4. Possible Side Effects**

Like all medicines ZIAXE may cause side effects in patients who are sensitive to its ingredients.

**Stop using ZIAXE and contact your doctor or emergency department of the nearest hospital IMMEDIATELY, if you experience any of the following:**

- Swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing; itchy, lumpy rash (hives)

All of these are very serious side effects. If you experience any of these side effects, you are seriously allergic to ZIAXE. You may require urgent medical attention or hospitalization.

All of these side effects are very rare.

Side effects are listed as follows:

Very common:	affects more than 1 user in 10
Common:	affects less than 1 to 10, but more than 1 in 100 patients.
Uncommon:	affects less than 1 to 100, but more than 1 in 1000 patients.
Rare:	affects less than 1 to 1000, but more than 1 in 10000 patients.
Very rare:	affects less than 1 user in 10000
Frequency not known:	cannot be estimated from the available data.

In adults:

Common side effects:

- Headache
- Dizziness
- Constipation
- Diarrhea

Uncommon side effects:

- High or low blood pressure
- Abnormal heart rhythm or decreased blood flow to the heart
- Change in the color of the vein and/or veins becoming larger
- Potassium level in the blood is unusually high or low
- High levels of sugar in the blood or in the urine
- Low levels of calcium in the blood
- High levels of the pigment bilirubin in the blood
- High levels of certain liver enzymes
- Elevated moods or feeling of anxiousness
- Sleepiness or trouble sleeping
- Decrease or loss of appetite
- Weakness, tiredness, fever or flu like symptoms
- Numbness, burning, prickling or tingling sensations on the skin
- Itchy skin rash
- Impaired vision or eye irritation
- Motion sickness (car sickness)

- Ringing in the ear
- Hiccups, flatulence, dry mouth or indigestion
- Abdominal pain
- Difficulty urinating
- Muscle pain
- Electrocardiogram abnormalities (QT prolongation)

Very rare side effects:

Allergic reactions to ZIAXE can include swelling of the lips, face, tongue or throat, having difficulty breathing or collapsing. You may also experience itchy, lumpy rash (hives). Burning or pain at the injection site.

### **In children and adolescents:**

#### **Common**

- Headache

#### **Uncommon**

- Dizziness
- Irregular body movements
- Abnormal heart beat
- Cough or shortness of breath
- Nose bleeding
- Itchy skin rash or hives
- Fire
- Pain in the infusion site

*If you get any side effects, including any site effects not listed in this leaflet, talk to your doctor or pharmacist.*

### **5. How to store ZIAXE**

*Keep ZIAXE out of the sight and reach of children and in its original container.*

Store ZIAXE below 25°C and protect from light and moisture.

**Do not freeze ZIAXE.** Do not thaw and use frozen products.

For single use. Discard unused portions of the solution in each vial.

**Do not use this medicine after the expiry date.**

*Do not use ZIAXE after the expiry date printed on the outer carton.*

Do not use ZIAXE if you notice any defects in the product or package.

*Do not dispose expired or unused medicines via the household waste! Send them to a waste collection system designated by local regulations.*

***Marketing Authorization Holder:***

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